

Application No. 10/533,009
Amendment Dated August 27, 2007
Reply to Office Action of April 27, 2007

REMARKS

In the Office Action dated April 27, 2007, pending claims 16-30 were examined with the result that all claims were rejected. The rejections made by the Examiner were non-final. In view of the following remarks, reconsideration of this application is requested.

§ 102 Rejections

The Examiner's principal objection is that claims 16-20, 22-24 and 28-30 are said to lack novelty over Schatz U.S. 6,027,509 (hereinafter referred to as "Schatz I"). The Examiner considers Schatz I to disclose a device for retrieval of a foreign body from a vessel of a patient, said device comprising: a flexibly resilient central shaft (110 or 22) having an axial channel capable of receiving a guide wire therein; balloon support means (46) extending from said central shaft and having a free end spaced therefrom; and inflatable balloon means (38) provided at said free end and arranged to expand inwardly towards said central shaft upon inflation; whereby in use said device is positioned such that a foreign body to be retrieved is located between said free end and said central shaft, and said balloon means is subsequently inflated to bear against the foreign body and hold it against said central shaft, such that the combined foreign body and device can be withdrawn from the vessel.

In arriving at this conclusion, the Examiner has interpreted the inflation lumen of the central shaft (110 or 22) of Schatz I as being equivalent to the axial channel of the central shaft defined in claim 16.

The applicant submits that the Examiner's objection is flawed, and is based upon a crucial misunderstanding of the disclosure of Schatz I, and indeed of the object of the present invention. The feature of Schatz I which the Examiner equates with the central shaft of the present invention as defined in claim 16 is stated as being either the feature labeled 110 or the feature labeled 22 in the drawings of Schatz I. However, on careful reading of Schatz I, it is apparent that the "central shaft 110" is not a feature of the stent retrieval devices of Schatz I's invention, but rather is the central shaft of the balloon

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catheter from which an undeployed stent is to be retrieved. As such, the balloon support means of Schatz I does not extend from this central shaft, as required by claim 16 of the present application.

Moreover, claim 16 states that in use, the balloon means is inflated to bear against the foreign body and hold it against the central shaft, such that the combined foreign body and device can be withdrawn from the vessel. In the case of Schatz I, this clearly cannot apply. The central shaft 110 does not form part of the stent retrieval device of Schatz I. Therefore, if the balloon means of Schatz I were inflated to hold the stent against the central shaft 110, it would be impossible to withdraw the stent retrieval device together with the stent from the vessel, without also removing the balloon catheter and the angioplasty guide wire. This is because the stent retrieval device itself would otherwise be required to be drawn along the stationary central shaft 100 against which the stent is compressed. Removal of the balloon catheter and the guide wire would mean that the surgical procedure was terminated, and a separate procedure would be required to relocate the stent in its correct position. By contrast, the stent removal device of the present invention can be picked up "off the shelf" as required during a procedure and utilized in combination with balloon catheters and other devices, including that described in Schatz I.

Once the stent has been successfully retrieved, the combined stent and device can be removed, leaving the balloon catheter or other device in place, along with the guide wire so that the surgical procedure can continue. It is this point in particular which makes the present invention particularly attractive to medical practitioners—and therein resides its inventiveness.

If one takes the Examiner's alternative position, that the central shaft in Schatz I is the feature labeled 22, then again this fails to meet the requirements of claim 16. Although the balloon means (46) of Schatz I does extend from this central shaft 22, the shaft 22 does not continue to extend through the center of the balloon support means (46). Consequently the balloon means are not arranged to expand inwardly towards said central shaft upon

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inflation, as required by claim 16. Moreover, it is not possible for the balloon means to bear against the foreign body and hold it against the central shaft, as required by the claim.

The remainder of the Examiner's objections based on Schatz I, as set forth on pages 3 and 4 of the Office Action rely on the premise that Schatz I deprives claim 16 of novelty. As the remainder of the claims are dependent upon claim 16 (with the exception of claim 30 which differs from claim 16 only in that it specifically refers to a stent rather than a "foreign body"), and it has been demonstrated that claim 16 is novel, then the Examiner's objections simply fall away. Nevertheless, it is notable that the Examiner's arguments against claims 20, 23 and 24 in particular are not well formulated in that they either identify no features of Schatz I which correspond to the claimed feature, or identify features in Schatz I which do not fully disclose or perform the same function as the features of the claims.

The Examiner has cited a further U.S. Patent No. 5,868,753, also in the name of Richard A. Schatz (referred to hereinafter as Schatz II") under § 102(e) against claims 16 and 21. Again, in citing this reference the Examiner has made an error in his understanding of the document. That is to say, the Examiner has interpreted the feature labeled 36 in Schatz II as being equivalent to the "central shaft" in claim 16 of the present application. However, on careful reading of Schatz II it is apparent that the feature labeled 36 is again part of the balloon catheter from which the undeployed stent is to be recovered, and consequently that this "central shaft 36" is not an element of the stent retrieval catheter of Schatz II's invention. As such, it is clear that the balloon support means of Schatz II does not extend from this central shaft, and that the balloon means are not arranged to expand inwardly towards said central shaft upon inflation. Moreover, the foreign body to be retrieved cannot be held against the central shaft when the device is in use. Were this the case, then the stent would again be compressed against the balloon catheter, and so it would not be possible for the stent retrieval catheter and stent to be withdrawn, without also removing the balloon catheter and guide wire. The Examiner's further objection on the basis of Schatz II against claim 21 relies on the premise that Schatz II deprives claim 16 of

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novelty. Again, since it has been demonstrated that the claim 16 objection is unsound, then this further objection also falls away.

§ 103 Rejections

In addition to the above discussed novelty objections, the Examiner has also raised a number of further objections against claims 25, 26 and 27 on the grounds of obviousness on the basis of a combination of Schatz I and two other documents, namely U.S. Patent 4,930,496 (Bosley) and U.S. Patent 5,910,154 (Tsugita).

Again, these obviousness objections rely on the basic premise that Schatz I discloses all of the features of claims 16, 23 and 24. However, as has been demonstrated above, Schatz I fails to disclose the feature of the stent retrieval device itself having a central shaft against which the stent can be compressed by the balloon means such that the combined stent retrieval device with the stent compressed against the central shaft can be removed from a vessel of a patient, without removing the balloon catheter or other operative devices, and the guide wire. Since neither Bosley nor Tsugita discloses such a feature, the Examiner's arguments that the invention could be arrived at by a combination of these documents is not well founded.

Summary

The novelty and inventiveness of the present invention resides in its ability to be utilized as and when required during a surgical procedure, and to be introduced and removed from the vessel as required, without requiring other surgical devices to be removed, which would necessitate termination of the procedure. Support for this is to be found in the passage at page 6, lines 15-18 of the international application as published. By contrast, the devices of Schatz would be required to be in place in preparation for the eventuality of a stent becoming misplaced, and would then necessitate the removal of all other surgical devices from the vessel upon recovery of the stent, thus terminating the procedure.

Applicant thus respectfully requests withdrawal of the 35 U.S.C § 102 and 35 U.S.C. § 103 rejections of the claims.

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An effort has been made to place this application into condition for allowance and such action has been earnestly requested.

Respectfully submitted,

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